

**Protocol**  
**In-Person Research Activity with COVID-19 Positive Participants or Suspected to Have COVID-19**

**Effective: 8 December 2020**

**Purpose:** The purpose of this In-Person Research Activity with COVID-19 Positive Participants or Suspected to have COVID-19 protocol is to provide guidance when conducting research activities that involve participants with COVID-19 or suspected to have COVID-19. This protocol will be **required** for all studies that include **off-campus** in-person research activities, such as in-person consent, recruitment, data collection, treatments, or interventions.

This protocol **does not allow** in-person research activities with COVID-19 positive participants or suspected to have COVID-19 to be conducted on the UAH campus. At no time should research participants with COVID-19 or suspecting to have COVID-19 be on the UAH campus.

**This protocol requires all researchers to work remotely** while conducting in-person research activities with COVID-19 positive participants or suspected to have COVID-19.

**Once in-person research activities are completed** with COVID-19 positive participants or suspected to have COVID-19 participants, where close contact has occurred (within 6 ft), **researchers must quarantine for 14 days before returning to campus.**

In-person research activities with COVID-19 positive participants or suspected to have COVID-19 may occur in settings such as hospitals, ambulatory clinic settings, community settings, off campus research laboratories, or other locations where research is conducted.

The PI must provide a **Letter of Support from either a Biosafety officer or Lab Supervisor** stating the protocols that are required in the institution where the research will take place. This will inform the IRB that the institution is aware of your study involving COVID-19 positive participants or suspected to have COVID-19. **If the institution does not have a Biosafety officer or Lab Supervisor who can provide oversight of the procedures UAH IRB approval will not be granted.**

If you are **submitting a new IRB application** that will include in-person research activities with COVID-19 positive participants or suspected to have COVID-19 this protocol must be included where appropriate in the application.

**IRB application submission:**

All IRB applications that intend to include in-person research activities with COVID-19 positive participants or suspected to have COVID-19 **must** include the following steps outlined below in the protocol. You may copy and paste the steps and how you will address the steps below and add to form 1 in the IRB application. This would include sections pertaining to How Subjects Will Be Selected and Recruited, Procedures for Attaining Informed Consent or Assent, and Description of Procedure.

## **Protocol: In-Person Research Activity Protocol with COVID-19 Positive Participants or Suspected to have COVID-19:**

### **1. COVID-19 Testing for Researchers**

- All UAH research team members who will come into contact with COVID-19 positive participants or suspected to have COVID-19 participants **must be tested prior to coming in contact with participants.**
- During the study while conducting in person research activities with COVID-19 positive participants or suspected to have COVID-19 participants the **researchers must be tested weekly.**
- Researchers must have a final COVID-19 test at the conclusion of in-person research activities with COVID-19 positive participants or suspected to have COVID-19 participants.
- Contact the UAH health services to be advised on how and when it is safe to return to campus.
- In your IRB application document how payment for COVID-19 testing will covered for the researchers.

### **2. Facility Considerations:** Research visits with participants and, if appropriate, collection of bio specimens will also be required to follow the facility's policy in place for those areas.

- **Signage:** A biohazard sign must be posted at the entrance to the area where collection of specimens will take place. This sign must include the biosafety level, a biohazard symbol, "Restricted Access Only," and "COVID-19+ Patient Samples"
  - The name and phone number of the PI or facility director, and lab entry procedures (including required personal protective equipment) must also be posted for entry. The researcher may consult the UAH Biosafety Officer for development of this signage.
- Disinfection of the area: The research team must document the facility's policy/protocol for disinfecting the facility following contact with participants confirmed or suspected COVID-19.
- The facility must provide a separate, individual waiting area for participants.
- Waiting areas should be arranged to allow for 6 feet of social distancing between seating. Seating can be marked off with signage promoting social distancing or a ribbon placed over the arms of the seat to prevent use.
- If the facility can't provide a separate waiting room, then the research team must escort the participant directly to examination/procedure room.
- Hand sanitizer should be freely available in all waiting areas and research areas.

### **3. Personal Protective Equipment (PPE).** The following minimal PPE must be worn when working with COVID-19+ patients and bio specimens.

- a. Protective gowns:
  - Disposable barrier gowns are required.
  - Dedicated shoes or disposable shoe covers
- b. Double gloves:

- Inner gloves should be inside the gown sleeve and outer gloves should cover the gown sleeves
  - The outer gloves are to be (i) disinfected or (ii) removed and replaced every time prior to exiting the biosafety cabinet.
  - Outer gloves should be replaced if their integrity is suspect or if they are visibly contaminated
  - Inner gloves are to be disinfected and removed prior to washing hands thoroughly and exiting the research area.
- c. Face/Eye Protection required:
- Eye protection (glasses or face shield)
  - N95 respirators (requires fit-testing through the facility).

\*Certain procedures may require additional PPE. Contact the UAH Biosafety Officer or facility director as appropriate.

4. Stringent handwashing is required with an antibacterial agent.
5. Maintain social distancing of 6 ft. when possible.
6. The researcher must provide a detailed description regarding the physical containment of bio specimens when bio specimens are collected from the participant. (This section will be reviewed by the UAH Biosafety Committee prior to UAH IRB approval.)
7. The researcher must document how waste (solid and/or liquid) will be managed and how the area will be decontaminated following disposal of waste products. Contact the UAH Biosafety Officer or the director of the facility where the research is conducted for guidance.
8. The researcher must have a spill kit and document the components of the spill kit. Contact the UAH Biosafety Officer for guidance and components required for a spill kit.
9. The researcher must document how accidents or spills will be handled.